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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/009,590

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Zhi Xian Chen

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03/07/2008

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WASHINGTON, DC 20005

EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

03/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

## Office Action Summary

**Application No.**

10/009,590

**Applicant(s)**

CHEN ET AL.

**Examiner**

Anne R. Kubelik

**Art Unit**

1638

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14 and 18-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-11, 13-14 and 18-30 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The indicated allowability of claims 19 and 23-30 is withdrawn in light of the new rejections below.
4. The rejection of claims 19-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment of claim 19.
5. The rejection of claims 1 and 3-5 under 35 U.S.C. 102(b) as being anticipated by Strickland (WO 97/12512) is withdrawn in light of Applicant's arguments.
6. The rejection of claims 1-6, 12-14, 18 and 20-22 under 35 U.S.C. 103(a) as being unpatentable over Strickland (WO 97/12512) is withdrawn in light of Applicant's arguments.

### ***Claim Rejections - 35 USC § 103***

7. Claims 1-2, 6-11, 13-14, 18-20, 23 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rangan et al (1993, US Patent 5,244,802) in view of Gawel et al (1990, Plant Cell, Tiss. Organ Devel. 23:201-204), and further in view of Price et al (1979, Plant 145:305-307).

The claims are drawn to a method of producing a transgenic cotton plant comprising exposing petiole explants to Agrobacterium comprising a DNA encoding a selectable marker and an exogenous protein, culturing the explants to induce callus formation, selecting transformed

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callus, culturing the selected callus in suspension culture to induce embryoid formation, and regenerating the embryoid into a plant.

Rangan et al teach culturing cotyledon or hypocotyl segments on MS media supplemented with 1-2 mg/l kinetin and 1-10 mg/l of the auxin NAA, with 20-30 g/l glucose as the only carbon source, to produce callus (column 8, lines 20-55; claims 1, 8-10). The callus is then grown in media supplemented with 0-1 mg/l cytokinin and 1-10 mg/l of the auxin NAA to induce formation of embryogenic callus (column 8, line 55, to column 9, line 5). Embryogenic calli can be developed in suspension culture over about 5 to 36 days in media containing 1-10 mg/l NAA, with sucrose as the only carbon source; this media is also used for selection of transformed callus that expresses the exogenous gene and for formation of embryoids (column 9, line 46, to column 11, line 60; claim 17). Embryo germination occurs on a media containing 500 mg/l casein hydrolysate and about 1.2 g/l  $\text{KNO}_3$  (column 9, lines 19-29; claim 1); casein hydrolysate is a nitrogen source containing both asparagine and glutamine. The resulting plantlets can grow on soil (claim 1).

Rangan et al disclose transformation of cotton plant segments with *Agrobacterium tumefaciens* harboring a vector comprising a selectable marker gene and an exogenous gene encoding a *Bacillus thuringiensis* toxin or resistance to glyphosate (Fig 11, 13). The plant cells were exposed to *Agrobacterium* in a medium with 2 mg/l NAA (column 14, lines 41-65), and were precultured prior to exposure to *Agrobacterium* (column 14, lines 10-15).

Rangan et al do not teach use of petioles as the explant material, use of 2,4-D as the auxin in the explant culturing step, use of a suspension culture in the embryogenic callus formation step, the lack of hormones in the exposing, selection, embryogenic callus formation, or embryoid

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formation media, or use of 3.8 g/l  $\text{KNO}_3$  and/or 500 mg/l asparagine and 1 g/l glutamine in the germinating media.

Price et al teach culturing callus in a hormoneless suspension culture to induce formation of embryogenic callus and embryoids (pg 305, right column, paragraphs 2-5; entire pg 306).

Gawel et al teach use of cotton petioles as the explant material and culturing the explants in media containing 0.1 mg/l 2,4-D and 0.1 mg/l kinetin (pg 202, left column). Gawel et al also teaches culturing callus in suspension culture to induce formation of embryogenic callus and embryoids, and that liquid media was preferable (pg 202, right column, paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the cotton transformation method taught by Rangan et al to use petioles as the explant material, to use 2,4-D as the auxin in the explant culturing step, to use a suspension culture in the embryogenic callus formation step, to use media lacking hormones in the exposing, selection, embryogenic callus formation, or embryoid formation steps, or to use 3.8 g/l  $\text{KNO}_3$  and/or 500 mg/l asparagine and 1 g/l glutamine in the germinating media. One of ordinary skill in the art would have been motivated to use a suspension culture in the embryogenic callus formation step because plants Gawel et al teaches that suspension culture was preferable (pg 202, right column, paragraph 2). One of ordinary skill in the art would have been motivated to try hormoneless media because Price et al teaches that hormones are not necessary (pg 306, right column, paragraph 2). One of ordinary skill in the art would have been motivated to use petioles as the explant material and 2,4-D as the auxin because of Gawel's success with them. One of skill in the art would have tried different concentrations of the hormones in the selection step, including 0.05 mg/l 2,4-D in the course of optimization of experimental parameters. One of

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ordinary skill in the art would have been motivated to try 3.8 g/l KNO<sub>3</sub> and/or 500 mg/l asparagine and 1 g/l glutamine in the germinating media in the course of optimization of experimental parameters.

8. Claims 3-5, 21-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rangan et al in view of Gawel et al and further in view of Price et al as applied to claims 1-2, 6-11, 13-14, 18-20, 23 and 26-30 above, and further in view of Tull et al (US Patent 6,242,257, filed May 1997).

The claims are drawn to a method of producing a transgenic cotton plant comprising exposing petiole explants to *Agrobacterium* comprising a DNA encoding a selectable marker and an exogenous protein, culturing the explants to induce callus formation, selecting transformed callus, culturing the selected callus in suspension culture to induce embryoid formation, and regenerating the embryoid into a plant, wherein either glucose is the sole carbon source in all media or wherein both glucose and sucrose are the carbon sources in the regenerating media.

The teachings of Rangan et al in view of Gawel et al and further in view of Price et al are discussed above. Rangan et al in view of Gawel et al and further in view of Price et al do not disclose glucose as the sole carbon source in all media or both glucose and sucrose as the carbon sources in the regenerating media.

Tull et al teach use of glucose is the sole carbon source in all media (column 18, lines 36-53) and use of both glucose and sucrose are the carbon sources in the regenerating media (Table 4). Tull et al teach use of the carbon source at a concentration of 30 g/l (Tables 2-4)

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of cotton transformation as taught by Rangan et al in view of

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Gawel et al and further in view of Price et al, to use glucose as the sole carbon source in all media or use both glucose and sucrose as the carbon sources in the regenerating media as described in Tull et al. One of ordinary skill in the art would have been motivated to do so because Tull et al teach that use of glucose as the sole carbon source reduces the necessity of frequent subculture (column 18, lines 48-53), and because young plants can be obtained on media containing both glucose and sucrose (claim 6). One of skill in the art would have tried different concentrations of sucrose and/or glucose, including 10 g/l of each of glucose and sucrose in the regenerating media in the course of optimization of the protocol.

### *Conclusion*

9. No claim allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Anne Kubelik, Ph.D.

March 12, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638